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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	PAPER NUMBER
1643	
MAIL DATE	DELIVERY MODE
12/21/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,702	KIM, RICHARD	
	Examiner	Art Unit	
	ANNE L. HOLLERAN	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4,8,10-15,18,22,27,30,34,36 and 47-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,4,8,10-15,18,22,27,30,34,36 and 47-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/2009; 09/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 2, 4, 8, 10-15, 18, 22, 27, 30, 34, 36 and 47-51 are pending and examined on the merits.

The elected species is ErbB2 for ErbB receptor, and measuring protein levels.

Information Disclosure Statement

The IDSs of 12/15/2009 and 9/17/2010 have been considered. See attached 1449s.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See page 42, line 23, for example.

Claim Rejections Withdrawn:

Claim Rejections - 35 USC § 112

The rejections of claims 2, 4, 8, 10-15, 18, 27, and 48 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment to the claims.

Claim Rejections - 35 USC § 102

The rejection of claims 2, 4, 8, 10, 12 13, 15, 22, 30, 34, 36, 47-51 under 35 U.S.C. 102(b) as being anticipated by Slamon (US 4,968,603; issued Nov 6, 1990) is withdrawn upon further consideration.

The rejection of claims 2, 4, 8, 10, 12, 13, 15, 22, 30, 34, 36, 47-51 under 35 U.S.C. 102(b) as being anticipated by Ross (US 5,994,701; issued Nov 30, 1999) is withdrawn upon further consideration.

Claim Rejections - 35 USC § 103

The rejection of claims 2, 4, 8, 10-13, 15, 22, 30, 34, 36, 47-51 under 35 U.S.C. 103(a) as being unpatentable over Slamon (supra) as applied to claims 2, 4, 8, 10, 12 ,13, 15, 22, 30, 34, 36, 47-51 above, and further in view of DiGiovanna (DiGiovanna, et al. Cancer Research, 55: 1946-1955, 1995) is withdrawn upon further consideration.

The rejection of claims 2, 4, 8, 10, 12, 14, 22, 30, 34, 36, 47-51 under 35 U.S.C. 103(a) as being unpatentable over Slamon (supra) as applied to claims 2, 4, 8, 10, 12 , 22, 30, 34, 36, 47-51 above, and further in view of Ballinger (US 6,387,638; issued May 14, 2002) is withdrawn upon further consideration.

New Grounds of Rejection:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 4, 8, 10-15, 18, 22, 27-30, 34 and 47-51 rejected under 35 U.S.C. 112, first paragraph, because the specification, for the broadly claimed invention. Claims 2, 4, 8, 10-15, 18, 22, 27-30, 34 and 47-51 are rejected under 35 U.S.C. 112, first paragraph, because the specification fails to reasonably provide enablement commensurate with the scope of the claimed invention. The specification does not enable one skilled in the art to which the claimed invention pertains, or with which it is most nearly connected, to make and use the full scope of the claimed invention.

Factors to be considered in determining whether undue experimentation would be required to practice the full scope of the claimed inventions are: 1) quantity of experimentation necessary; 2) the amount of direction or guidance presented in the specification; 3) the presence or absence of working examples; 4) the nature of the invention; 5) the state of the prior art; 6) the relative skill of those in the art; 7) the predictability or unpredictability of the art; and 8) the breadth of the claims. See In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

Independent claim 2 is drawn to a method for determining the prognosis of a cancer in a subject that has been previously treated with radiotherapy or chemotherapy for a cancer that is associated with an aberrant expression and/or activity of ErbB-1. The scope of the term “a cancer that is associated with an aberrant expression and/or activity of ErbB-1" is broad and includes

cancers known to express ErbB-1, such as the cancers listed in dependent claim 8 (non-small-cell lung cancer, breast cancer, head and neck cancer, prostate cancer, bladder cancer, ovarian cancer, colorectal cancer and glioblastoma). Independent claim 22 is drawn to a method for improving the effectiveness of cancer treatment in subject that has been previously treated with a treatment regimen so as to achieve remission. Claim 47 is drawn to a method for improving the effectiveness of cancer treatment in a subject that has been previously treated with a treatment regimen so as to achieve remission. The active steps of the claimed methods are measuring a level of at least one ErbB receptor in a sample obtained from the subject during a period of remission and comparing the level to a standard level. In claim 47 there is an additional step f treating the subject who has an elevated level of at least one ErbB receptor relative to the standard level with an additional treatment.

The elected species of ErbB receptor is ErbB-2 (see restriction and response of 5/1/2008 and 7/22/2008).

Ross (Seminars in Cancer Biology, 9: 125-138, 1999) summarizes studies that have looked at the use of ErbB-2 (HER-2) expression measurements and prognosis for breast cancer (see Table 2, pages 127-129). In some cases measurement of ErbB2 protein levels correlates with response to therapy and in some cases this has not been found to be the case. Breast cancer is considered to be a cancer that is associated with an aberrant expression and/or activity of ErbB-1 because ErbB-1 is detectable in breast cancers (see Bundred, N.J., Cancer Treatment Reviews, 27: 137-142, 2001, page 140, left to right col.). Ross does not teach studies in which ErbB-2 is measured in samples from subjects in remission. The correlation is determined from tumor samples taken before treatment. Because the claims require that the patient be in a period

of remission, the claims read on methods using a marker such as plasma or serum erbB-2 (which is the extracellular domain fragment of erbB-2), because a period of remission assumes there is no tumor tissue or little tumor tissue to be used as a sample (specification defines “remission" as a period during which the symptoms of a cancer have been reduced or eliminated, as remission is ordinarily defined in the oncology art; see page 7). Further, the specification teaches that a level of an ErbB receptor may correspond to abundance of a fragment of an ErbB receptor protein (see page 8). Revillion (Revillion, F., et al. European Journal of Cancer, 32A(2): 231-234, 1996) teaches an example of a study where ErbB-2 is measured in plasma samples from patients treated with chemotherapy where there is no relationship between plasma erbB-2 levels and response to therapy (see page 233, right col.).

The specification provides little guidance with respect to demonstrating that measurement of erbB-2 levels in a patient during a period of remission is predictive of an increased risk of metastasis, recurrence or relapse of the cancer. The specification provides no guidance with respect to demonstrating that measurement of erbB-2 levels in a patient during remission may be used to decide what treatment to administer to a patient during remission.

Given the findings in the prior art that measurement of ErbB-2 is not clearly predictive of breast cancer prognosis, and given the lack of working examples in the specification to provide guidance, one of skill in the art would have to engage in further experimentation to determine which cancer to target in a prognostic method. Given that a subset of the claims contain a treatment step, the further experimentation would be in field of cancer treatment of a patient in remission. This further experimentation would be undue experimentation with respect to the use of ErbB-2 measurements and cancer prognosis, because the prior art is not clear on the role of

ErbB-2 measurements in the field of cancer prognosis, and because the specification does not provide an guidance to supplement the unpredictability found in the prior art.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22, 27, 30, 34, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoffmann (Hoffmann, T.K., et al., Oral Oncology, 37: 50-56, 2001).

Claim 22 is drawn to a method for improving the effectiveness of cancer treatment in a subject, which subject has been previously treated with a treatment regimen so as to achieve remission, the method comprising the active steps of measuring a level of at least one ErbB receptor in a sample obtained from the subject during a period of remission and comparing the level measured to a standard level. The cancer may be a cancer associated with an aberrant expression and/or activity of ErbB-1 (claim 27). The ErbB receptor that is measured may be ErbB-2 (elected species; claim 30). The cancer may be non-small-cell lung cancer, breast cancer, head and neck cancer, prostate cancer, bladder cancer, ovarian cancer, colorectal cancer and glioblastoma (claim 34). The level of ErbB receptor is measure using an ErbB receptor probe (claim 36).

Hoffmann teaches measuring serum ErbB-2 levels (as well as ErbB-1 levels) in patients 6 weeks after being treated with surgery for squamous cell carcinoma of the head and neck (see

page 51, left column; see Figure 3; see Table 1 "Serological Follow-up". The fact that the patients had been treated with surgery 6 weeks prior to a measurement of serum erbB-2 meets the limitation of a measuring a level of at least one ErbB receptor in a sample obtained from the subject during a period of remission. Hoffmann teaches comparison to a control (page 52, left to right column). Therefore, Hoffmann teaches a method that is the same as that claimed.

Claims 22, 27, 30, 34, 36, 47-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Streckfus (US Patent 6,294,349; issued Sep. 25, 2001).

Streckfus teaches and claims a method of measuring ErbB-2 levels in saliva samples from post-operative breast cancer patient, which reads on a patient in remission. Streckfu teaches and claims further treating the patient depending on the determination of biomarker levels (one biomarker is c-erbB-2; see claims 7-10). Therefore, Streckfus teaches and claims methods that are the same as that claimed.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu, can be reached on (571) 272-0839. Any inquiry of a general nature or relating to the status

of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

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